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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,144	07/26/2005	Gretel Sass	35-286	2428

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EXAMINER

ARNOLD, ERNST V

ART UNIT PAPER NUMBER

1616

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/524,144	SASS, GRETEL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ernst V. Arnold	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>02/11/05, 04/05/05</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

The Examiner acknowledges receipt of application 10/524,144 filed on 07/26/2005. Claims 1-8 have been cancelled and new claims 9-17 have been added. Accordingly, claims 9-17 are presented for examination on the merits.

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Claim Objections***

Claim 11 is objected to because the proper art recognized spelling of "bussulphan" is busulphan or busulfan.

Claim 16 is objected to because the proper spelling of "glatriamer" is glatiramer.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Openshaw et al. (Biology of Blood and Marrow Transplants 2000, 6, 563-676).

Openshaw et al. disclose a method of treatment for people with primary or secondary progressive multiple sclerosis comprising a preparatory regimen of oral busulfan (1 mg/kg  $\times$  16 doses) and cyclophosphamide (an amino immunomodulatory substance) (120 mg/kg) thus reading on instant claims 9-11, 15 and 17 (Abstract; page 564, patient eligibility and preparatory regimen and supportive care). Openshaw et al. disclose that 3 patients received interferon treatment and then the busulfan/cyclophosphamide regimen thus anticipating instant claim 16 (Page 565, results and page 567, Table 3).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Openshaw et al. (Biology of Blood and Marrow Transplants 2000, 6, 563-676).

The reference of Openshaw et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Openshaw et al. do not expressly disclose a method wherein the treosulphan or derivatives are administered in the amount of 1 to 10 grams; 3 to 9 grams or 5 to 8 grams per  $m^2$  body surface area. As discussed above, Openshaw et al. disclose a dosage regimen in terms of body weight. For the sake of argument, the Examiner calculates that for a 180 lbs ( $180/2.2 = 81.8$  kg) person that would mean 81.8 mg administered over 16 doses or 1.308 g per person that weighed 180 lbs. The average female has 1.6 square meters of skin and the average male has 1.8 square meters of skin thus resulting in a dosage of:  $1.308/1.6 = 0.8125$  g/ $m^2$  to  $1.308/1.8 = 0.726$  g/ $m^2$ . For Applicant's benefit, the Examiner has attached a reference (reference U) that discusses the surface area of human skin.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to increase the dosage of treosulphan or derivatives thereof for the purpose of providing the proper dosage to patients suffering from multiple sclerosis and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because one of ordinary skill in the art would know to calculate the proper dosage amounts for obese people who would have a larger than normal body surface area and require more of the medicament. It is also within the purview of one of ordinary skill in the art to select drugs effective in the treatment of multiple sclerosis in combination such as busulfan derivatives and glatiramer acetate. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea

of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teaching of the cited reference.

### ***Conclusion***

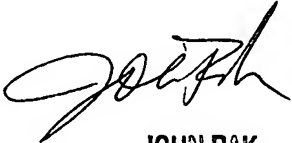
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA



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